

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

24 MAR 2005

Applicant's or agent's file reference 088/03504	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/IL03/00769	International filing date (day/month/year) 25 September 2003 (25.09.2003)	Priority date (day/month/year) 25 September 2002 (25.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/08 and US Cl.: 606/153		
Applicant BY-PASS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

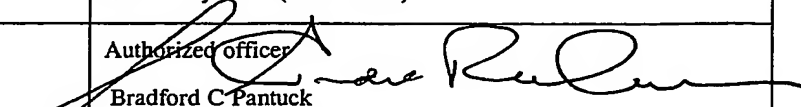
2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 22 April 2004 (22.04.2004)	Date of completion of this report 04 January 2005 (04.01.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Bradford C. Pantuck Telephone No. (703) 308-0858

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/IL03/00769

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☐ the international application as originally filed.
- ☒ the description:  
pages 1-31 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 32, 34-37, 39 as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages 33, 38, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-23 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>8, 11, 16-23, 26-30, 32-57</u>	YES
	Claims <u>1-7, 9, 10, 12-15, 24, 25, 31</u>	NO
Inventive Step (IS)	Claims <u>8, 11, 16-23, 26-30, 32-48, 50-57</u>	YES
	Claims <u>1-7, 9, 10, 12-15, 24, 25, 31, 49</u>	NO
Industrial Applicability (IA)	Claims <u>1-57</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-7, 9, and 10 lack novelty under PCT Article 33(2) as being anticipated by Publication No. US 2002/0099394 A1 to Houser et al. Regarding Claims 1-3, 6, 7, and 9 Houser discloses in Figures 53a and 53b and in Paragraph [0176] a plurality of leg confiners (four radially extendable protrusions at the distal end of 440) having slots (442) between them. Houser also discloses a coupler (34), which couples a graft to the leg confiners {see para. [0176]}. The *leg confiners are configured to move in an inner direction* ["the fittings are compressible into a low profile for insertion into a vessel"], particularly when "splittable tubing (not shown)" is slid over the leg confiners {see para. [0176]}. This splittable tubing is a control for splitting at least a portion of the system. Various spacing distances can be maintained between the confiners and a graft vessel.

Regarding Claim 4, the leg confiners are shaped in a circle.

Regarding Claim 5, the configuration is used for an end-to-side anastomosis procedure, so a graft is certainly a part of the procedure.

Regarding Claim 10, each confiner is capable of receiving a single leg.

Claims 12-15, 24, 25, and 31 lack novelty under PCT Article 33(2) as being anticipated by Publication No. US 2002/0022852 A1 to Dakov. Dakov discloses a system that, although not intended for the purpose outlined by Applicant is certainly capable of such an intended use. Dakov discloses a coupler (313) at the proximal end and two elongated leg confiners (306), which move in an inward direction [see Figures 26A and 26B]. Dakov's instrument has all of the claimed structure of Applicant's invention.

Regarding Claim 31 Dakov's instrument had a body (312) capable of receiving a connector, a handle (the user can grasp the instrument at its proximal end), and by rotating the elongated arms (306) the user has control over the mechanism.

Claim 49 lacks an inventive step under PCT Article 33(3) as being obvious over Publication No. US 2002/0099394 A1 to Houser et al. It would be obvious to put Houser's arrangement including a plurality of leg segments (440) and band (34) in a sterile package as is well-known in the medical art.

Claims 8, 11, 16-23, 26-30, 32-48, and 50-57 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed inventions.

Claims 1-57 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

47. An anastomotic connector kit, comprising:

a plurality of leg segments arranged in a generally circular configuration; and  
a plurality of leg locking segments, each adapted to be locked to one leg,  
wherein, wherein at least two legs at opposing sides of said circle are configured to be

5 stiffer than other of said legs.

48. An anastomotic connector kit, comprising:

a plurality of leg segments arranged in a generally circular configuration; and  
a plurality of leg locking segments, each adapted to be locked to one leg,

10 wherein, wherein at least two legs at opposing sides of said circle are configured to  
bend radially out more than other of said legs.

49. A connector kit, comprising:

a sterile package;

15 a connector having a plurality of forward legs; and

a band radially compacting said legs towards a center, within the sterile package.

50. A method of mounting a graft on a connector delivery system capsule, comprising:

axially splitting said capsule;

20 laying said graft in said capsule;

closing said capsule; and

mounting said capsule on a connector of said capsule.

51. Apparatus for mounting a graft on a spoilable graft capsule, comprising:

26 a splittable connector capsule;

a body including a receptacle large enough to hold a split capsule and including a slot

in its side; and

a control which selectable opens said body so said capsule can open.

30 52. Apparatus according to claim 51, wherein said control actively splits said capsule.

53. Apparatus according to claim 51, wherein said body is adapted to radially compact legs

10. A leg compacting system according to claim 1, wherein each confiner is configured to receive a single leg.

11. A leg compacting system according to claim 1, wherein said plurality of leg confiners are configured to release legs when moved outwards, said release being not simultaneous for all legs.

12. A leg compacting system for compacting inwards a group of legs of an anastomotic connector towards a central location thereof, comprising:

10 a coupler for coupling to a delivery system on which said connector is mounted; and  
a plurality of leg confiners, configured to selectively move in an inward direction and to automatically engage said legs while moving inwards.

13. A leg compacting system according to claim 12, wherein each leg confiner is configured to receive a plurality of legs.

14. A leg compacting system according to claim 12, wherein each leg confiner is configured to receive a single leg.

15. A leg compacting system according to claim 12, wherein said motion is radial.

16. A leg compacting system for compacting inwards a group of legs of an anastomotic connector towards a central location thereof, comprising:

25 at least one wire arranged to selectively move inwards, from a position outwards of the legs, thereby compacting the legs; and  
a controller which is operative to selectively moving said wire.

17. A leg compacting system according to claim 16, wherein said wire is adapted to engage said legs near a hook section of the legs.

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18. A leg compacting system according to claim 16, comprising at least two wires configured to compact the legs simultaneously from two directions.